UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
THIS DOCUMENT RELATES TO: ALL ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

PLAINTIFFS' LOCAL RULE 56.1 COUNTER-STATEMENT OF DISPUTED MATERIAL FACTS IN OPPOSITION TO THE J&J DEFENDANTS' POST-REMAND MOTIONS FOR SUMMARY JUDGMENT

Pursuant to Local Rule 56.1, James Shepley, on behalf of the estate of Therese Shepley, and Larry Young, on behalf of the Estate of Patricia Young, by their undersigned counsel, submit this Counter-Statement of Disputed Material Facts in Opposition to the J&J Defendants' Post-Remand Motions for Summary Judgment.[1]

Undisputed Facts Concerning Knowledge of Spreads[2]

Statement 1. Plaintiffs concede, and the Court found, that "it is undisputed that the market understood and expected a 20 to 25 percent formulaic markup from WAC to AWP."

Counter-Statement 1. Conceded to the extent such statements apply to Class 2 and Class 3; disputed to the extent the J&J Defendants imply that "the market" or "knowledgeable insiders" includes the members of Class 1. In addition, this expectation is irrelevant to

[1] The J&J Defendants' 56.1 Statements in Support of their Massachusetts motion and their nationwide motion are identical. Plaintiffs set forth those statements and their counter-statements only once.

[2] These subtitles are taken from J&J's Local Rule 56.1 Statement. Plaintiffs' use of them for their Counter-Statement is for the convenience of the Court and should not be interpreted as an endorsement of those statements.

Remicade, where Centocor set the AWP at 30% above WAC. *See* Ex. 1 (McHugh Dep. (4/29/05) at 134:11-135:10).[3]

Class 1 could not have had such an expectation. Medicare beneficiaries were the "vulnerable victim[s] of [the] strategy of 'marketing the spread' because when the AWP was raised, the Medicare patient was required to make a co-payment of 20 percent of the inflated AWP (or AWP-5% after 1998)." *In re Pharm. Indus. Average Wholesale Price Litig.* ("*In re AWP*"), 491 F. Supp. 2d 20, 33 (D. Mass. 2007).

> Medicare required that doctors charge Medicare recipients the 20 percent co-pay based on AWP. Most of the patients who required the drugs at issue in this case were quite ill with life-threatening diseases like cancer. The high stakes of treatment decisions and the corresponding trust patients had to place in their doctors rendered it highly unlikely that patients would switch physicians based on drug prices, further reducing any price-based competition. Pharmaceutical manufacturers knew that this pricing system resulted in physicians deciding to prescribe drugs at least partly based on their profitability, called "return to practice," instead of solely on the therapeutic effects of the drugs.

In re AWP, 252 F.R.D. 83, 89 (D. Mass. 2008).

J&J sought to hide from Medicare beneficiaries and other members of the public that it marketed Procrit and Remicade based on the spread and that its AWPs for those drugs were not real numbers. OBI knew that consumers were unaware of the discrepancy between AWP and average acquisition cost, and indeed would have been unhappy to learn of it. In an e-mail from Cathleen Dooley to Richard Moran dated January 6, 1998, Ms. Dooley highlighted that patients would be surprised to learn that physicians bill patients 20% off AWP, rather than off the lower acquisition cost: "*This will be a sensitive issue because the physician is able to bill Medicare*

[3] All exhibits to this Counter-Statement are attached to the Declaration of Steve W. Berman submitted herewith.

and the patient off of AWP; the patient's 20% co-pay is higher than it would be if it was billed off of acquisition cost (public relations' issue)." Ex. 2 (PX 259 at 58843) (emphasis added).

Medicare beneficiaries and other consumers did not know what AWP meant or that it was inflated, but they expected AWP to be a real price. Anna Choice testified that "whatever system is used as a basis for calculating my co-payment should be fair and accurate and not subject to manipulation." Ex. 3 (Anna Choice Tr. Aff., ¶ 18). "I feel it is unfair for drug companies to publish prices that have no real meaning, the effect of which is to cause me and others like me to pay more for those drugs." *Id*. at ¶ 19.

> I understand that defendants say that their published prices are like a sticker price on a car. However, to me a drug company that creates a false price knowing that my life depends on the drugs and that I must pay for them stands in different shoes than a car manufacturer. In addition, I am not aware of any situation where a car manufacturer offers discounts of 30%, 60% or even over 300% off sticker price.

Id. at ¶ 20. Similarly, Rebecca Anne Hopkins testified that "I do not know why BMS or other manufacturers would try to impose higher costs on me, but I think it is very unfair. Average folks like me have to rely on the honesty of those setting prices." Ex. 4 (Rebecca Anne Hopkins Tr. Aff., ¶ 14).

Larry Young likewise testified that:

> My wife and I relied on the advice of my wife's doctors and their facilities to be fair in their pricing of prescription medications and to comport with all ethical, moral, medical, regulatory and legal standards with respect to their medical care and treatment and their bills.
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> * * *
>
> My wife and I did not know if (or to what extent) her doctors or their facilities profited from the sale of prescription medications, as we were never told.

Ex. 5 (Apr. 7, 2006 Larry Young Decl., ¶¶ 7, 11). James E. Shepley further testified that "I relied on the advice of my doctors and their facilities to be fair in their pricing of prescription medications and to comport with all ethical, moral, medical, regulatory and legal standards with respect to their medical care and treatment and their bills." Ex. 6 (Apr. 7, 2006 James Shepley Decl., ¶ 7).

Statement 2. Plaintiffs concede, and the Court found, that "payors were aware there was some discounting from WAC." The formulaic markup, coupled with modest discounts, resulted in a marketplace expectation of spreads in the range of approximately 30%.

Counter-Statement 2. Conceded to the extent such statements apply to Class 2 and Class 3; disputed as applied to Class 1. Medicare beneficiaries were the "vulnerable victim[s] of [the] strategy of 'marketing the spread' because when the AWP was raised, the Medicare patient was required to make a co-payment of 20 percent of the inflated AWP (or AWP-5% after 1998)." *In re AWP*, 491 F. Supp. 2d at 33.

> Medicare required that doctors charge Medicare recipients the 20 percent co-pay based on AWP. Most of the patients who required the drugs at issue in this case were quite ill with life-threatening diseases like cancer. The high stakes of treatment decisions and the corresponding trust patients had to place in their doctors rendered it highly unlikely that patients would switch physicians based on drug prices, further reducing any price-based competition. Pharmaceutical manufacturers knew that this pricing system resulted in physicians deciding to prescribe drugs at least partly based on their profitability, called "return to practice," instead of solely on the therapeutic effects of the drugs.

In re AWP, 252 F.R.D. at 89.

J&J sought to hide from Medicare beneficiaries and other members of the public that it marketed Procrit and Remicade based on the spread and that its AWPs for those drugs were not real numbers. OBI knew that consumers were unaware of the discrepancy between AWP and average acquisition cost, and indeed would have been unhappy to learn of it. In an e-mail from

Cathleen Dooley to Richard Moran dated January 6, 1998, Ms. Dooley highlighted that patients would be surprised to learn that physicians bill patients 20% off AWP, rather than off the lower acquisition cost: "*This will be a sensitive issue because the physician is able to bill Medicare and the patient off of AWP; the patient's 20% co-pay is higher than it would be if it was billed off of acquisition cost (public relations' issue).*" Ex. 2 (PX 259) (emphasis added).

Medicare beneficiaries and other consumers did not know what AWP meant or that it was inflated, but they expected AWP to be a real price. Anna Choice testified that "whatever system is used as a basis for calculating my co-payment should be fair and accurate and not subject to manipulation." Ex. 3 (Anna Choice Tr. Aff., ¶ 18). "I feel it is unfair for drug companies to publish prices that have no real meaning, the effect of which is to cause me and others like me to pay more for those drugs." *Id*. at ¶ 19.

> I understand that defendants say that their published prices are like a sticker price on a car. However, to me a drug company that creates a false price knowing that my life depends on the drugs and that I must pay for them stands in different shoes than a car manufacturer. In addition, I am not aware of any situation where a car manufacturer offers discounts of 30%, 60% or even over 300% off sticker price.

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Statement 3. Plaintiffs concede, and the Court found, that the government shared the market's understanding of spreads in the range of 30%.

Counter-Statement 3. Disputed. The Government could not have had this understanding – especially about J&J's drugs – because J&J sought to conceal that information. In 2000, an OBI manager noted that the advantages for taking a price increase include "Greater discounting flexibility" and "Higher reimbursement from private payors – Possible positive perception from Physicians." *See* Ex. 26 (PX 244). OBI was aware that "there was a significant difference between AWP and acquisition price" and that should Medicare conduct a survey of prices, it would lower reimbursement. Ex. 8 (Trial Tr. Day 7 at 18 (Dooley)); Ex. 9 (PX 339). OBI was also aware that Medicare did not know Procrit's actual costs that were available to various providers. Ex. 8 (Trial Tr. Day 7 at 23 (Dooley)); Ex. 2 (PX 259). Further, OBI was aware that the only way Medicare could determine Procrit's market price was to request invoices from each provider, a system that would be "very cumbersome. . . ." *Id*. OBI was aware that Procrit's AWP caused increased costs to both Medicare and consumers. Cathy Dooley stated that "[t]his will be a sensitive issue because the physician is able to bill Medicare and the patient off of AWP. The patient's 20 percent copay is higher than it would be if it was billed off acquisition cost (public relations issue)." *Id*. at 27-28 (Dooley); Ex. 2 (PX 259 at 843). And Ms. Dooley

admitted that the true spread between Procrit's physician acquisition price and its AWP could be as much as 30 to 35%. Ex. 8 (Trial Tr. Day 7 at 88-89 (Dooley)). Despite knowing all of these facts, J&J did not disclose any of them to the Government.

Instead, when discussing Remicade costs with health plans, Centocor was careful not to reveal the physicians' acquisition cost, but only to reference the AWP price. Centocor's Cost Minimization Model or Cost Comparison Model software was used with health plans to encourage them to provide reimbursement for Remicade. Ex. 27 (PX 285). That software only references AWP, not WAC or acquisition cost. Centocor did not show health plans their various marketing tools that revealed physician acquisition prices or profit. Ex. 28 (Trial Tr. Day 5 at 83-84 (Hoffman)).

Centocor's Senior Director for Reimbursement Services, Michael Ziskind, articulated Centocor's policy of hiding acquisition prices from Third-Party Payors and Class members in a July 6, 1999 memo on the background of AWP and spread. Ziskind explained that the "'cost of therapy' varies widely based on the audience." Ziskind then explained Centocor's strategy was to not mention both wholesaler cost and AWP in the same conversation, because to do so would "set payers' expectations too low" and would "highlight spread more than we would like." Ex. 29 (PX 260).

On the one occasion where Centocor did report the price of Remicade to the Federal government, it hid the truth. When Centocor applied for a specific J-Code for Remicade, the application asked for Remicade's wholesale price. Centocor responded by saying that the wholesale price was AWP and that the retail price was equivalent to WAC. Ex. 30 (PX 261). Those statements were directly contrary to the fact that Remicade's WAC, not AWP, was

effectively the wholesale price. Ex. 28 (Trial Tr. Day 5 at 59:14-17 (Hoffman) (wholesale price close to WAC) and 59:21-25 (Remicade had no retail price)).

At trial, Centocor highlighted the fact that it worked with insurers to help them lower their cost of infusing Remicade, specifically citing to work done with Aetna. *Id*. at 103-07. However, at the same time, Centocor was also telling its physician customers to threaten Aetna by saying the doctors would send Remicade treatments back to the hospital unless Aetna raised reimbursement rates. Ex. 31 (PX 302 at 32731). Both Centocor and OBI's rebate contracts contained confidentiality clauses, which prevented the parties receiving rebates from revealing the amount, or even the existence of rebates on Remicade or Procrit. Ex. 32 (DX 2804 (sec. 1.5 and 3.1)).

Statement 4. Plaintiffs concede that Dr. Hartman's 30% liability yardstick is appropriately applied to Medicare.

Counter-Statement 4. Disputed. Even though Medicare may have known about 30% spreads, it could not act quickly to remedy the effects of J&J's conduct. *See In re AWP*, 491 F. Supp. 2d at 31 ("neither the third party payors nor the government could move quickly or effectively to fix the problem."); *id*. at 94-95 ("Moreover, defendants knew that neither the government nor the TPPs could do much to change the AWP reimbursement benchmark because they were locked into the nationwide reimbursement scheme established by statute or contract."). Therefore, Dr. Hartman's 30% yardstick is not appropriately applied to Medicare.

In addition, application of that yardstick is not appropriate because J&J concealed its conduct from the Government. AWP, as set forth in the Medicare statute, 42 U.S.C. § 1395u(o), is intended to mean "the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies." *See In re AWP*, 460 F. Supp. 2d 277, 278 (D. Mass.

2006). AWP is not a term of art "for any price the pharmaceutical industry places in the industry publication." *Id.* at 287.

Both Centocor, which manufactures, markets and sells Remicade®, and Ortho Biotech Products, L.P. ("OBI"), which manufactures, markets and sells Procrit®, knew that Medicare Part B payments were based on AWP. *See* Ex. 7 (PX 249) (Centocor); Ex. 8 (Trial Tr. Day 7 at 17 (Dooley) ("the average wholesale price was what Medicare was reimbursing off of.")). J&J fully understood the Medicare reimbursement system and its impact on physician choices. *In re AWP*, 491 F. Supp. 2d at 55. For example, a 1993 memo emphasized that the "goal is to keep the physician 'whole' i.e. whole on the 80% as there is a fear that they will not be reimbursed on the remaining 20%." *Id*. (citing PX 339 at 61807). A 1999 examination of reimbursement scenarios showed that a physician's profit per patient, for a twenty week course of Procrit, could range from a loss of $304 to a gain of $1,520 depending on the percentage of the copayment collected. *Id*. (citing PX 346 at 60861). A 1996 McKinsey & Company consulting report for OBI quoted a doctor as stating that "[m]y practice makes $6-8,000 per month on Procrit." *Id*. (quoting PX 334 at 6790). The report advised that "[Ortho Biotech] must preserve positive economics for physicians." *Id*. (quoting PX 334 at 6810). Significantly, in 1997, when Medicare decided to change Part B reimbursement from 100% of AWP to 95% of AWP, OBI responded by making its first price increase since the launch of Procrit. *Id*. In February 1997, OBI increased the prices on the most popular unit of Procrit by 3.5% and then in January of 1998 increased the prices an additional 1.8%. *Id*. (citing PX 237, 238). The result was that physicians would receive essentially the same reimbursement amount for Procrit after Medicare reduced its reimbursement percentage of AWP. *Id*.

Despite having this knowledge, J&J concealed from the Government its true prices. Ms. Dooley testified that she had conversations with officials from CMS about the true prices for Procrit. Ex. 8 (Trial Tr. Day 7 at 16 (Dooley)). Despite the fact she regularly wrote to her superiors, Ms. Dooley has no notes or memos regarding her meetings. *Id*. at 24-25. Nor do any of the millions of documents produced by CMS reflect such conversations. However, as discussed below, Dooley authored several memoranda expressing concerns about the Government learning of Procrit's true price. On August 6, 1996, Ms. Dooley warned that if the Government conducted a survey and, in fact, learned of the "significant" discrepancy between AWP and actual acquisition cost for non-End Stage Renal Disease treatment, the likely consequence would be that the Government would take action to lower the reimbursement rate for Procrit providers in non-dialysis. Ex. 9 (PX 339 at 61805). When OBI considered taking a price change, it was careful not to raise its list price above that of Epogen because OBI did not want to raise the undue attention of HCFA, which could trigger a pricing survey or investigation by the Government. For example, in a memorandum dated December 2, 1997, Ms. Dooley highlighted several key "Implications for Increase over Parity" including: (1) "Change in list price could trigger a drug pricing survey by HCFA," (2) "You may have a pricing survey anyway, but raising red flags could trigger it earlier," and (3) "Consequence of pricing survey could be acquisition, FSS or ESRD reimbursement rate in non-dialysis." Ex. 10 (PX 262 at 61052). A day later, Gary Reedy sent a memorandum recommending against OBI taking a price increase above parity for similar reasons: "We feel creating a higher list price could raise undue attention and possibly trigger a drug survey by HCFA because of the difference in list price for the two identical drugs, Procrit and Epogen." Ex. 11 (PX 263). Ms. Webb agreed that the risk of

triggering a government price survey was a sound basis for advising against OBI taking a greater price increase at that time. *Id.*; Ex. 12 (Webb Dep. at 103:9-15).

Ms. Dooley, in an e-mail dated January 7, 1998, explained that Medicare was in the dark as to the actual average acquisition price of Procrit, because if the Government actually knew, it would lower reimbursement to providers. "This was fortunate for us. The only way they could correct the current system is to require an invoice be submitted with each Medicare claim that is sent in. This would be very cumbersome and the medical providers and Medicare carriers have rejected this … Right now they do not know what the cost is for different providers." Ex. 2 (PX 259 at 58842).

OBI carefully tracked Congressional developments with respect to changes in AWP reimbursement. By April 1997, it was worried that a reduction in AWP would "impact the windfall that the physician receives for the drug" and that a change in reimbursement would impact "sales." Ex. 13 (PX 365).

To mitigate the impact of a reduction in AWP effective January 31, 1998, OBI raised the price of Procrit in January 1998 by 1.7%. Ex. 11 (PX 263); Ex. 8 (Trial Tr. Day 7 at 38 (Dooley)). When combined with an increase of 3.5% in 1997, these two increases exceeded the 5% reduction in AWP Congress implemented in January 1998. Ex. 8 (Trial Tr. Day 7 at 38-39 (Dooley)).

Statement 5. According to Michael K. Loukes, former Chief of the Health Care Fraud Unit for the U.S. Attorney's Office in Boston, Congress expected AWP to reflect a formulaic markup over WAC.

Counter-Statement 5. Conceded. However, the statement on which the J&J Defendants rely for Statement 5, as argument of counsel, is inadmissible hearsay and cannot be relied on in support of a motion for summary judgment. *See Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990) ("Hearsay evidence, inadmissible at trial, cannot be considered on a motion for

summary judgment."); *Copy Cop. v. Trask Printing*, 908 F. Supp. 37, 41-42 (D. Mass. 1995) (Saris, J.) (ruling that "[hearsay] evidence would not be admissible at trial and thus cannot be considered in a motion for summary judgment.").

Undisputed Facts Concerning the Spreads on Procrit® and Remicade®

Statement 6. Plaintiffs concede, and the Court found, that the spreads on Procrit were always less than 30%.

Counter-Statement 6. Conceded only to the extent that "spreads" means the spreads between AWP and ASP as articulated in Direct Testimony of Raymond S. Hartman, Dkt. No. 3296, Attachment G.3.c, Ex. 14. The "spread" might, alternatively, be measured by the total dollars since providers were motivated by the dollars that he/she might receive by prescribing one drug rather than another. Plaintiffs do not concede the spreads used by Dr. Hartman at the Class 2/Class 3 trial are the spreads that should be applied to Class 1.

Statement 7. Plaintiffs concede, and the Court found, that the spreads on Remicade "hovered very near to 30% throughout the class period."

Counter-Statement 7. Conceded only to the extent that "spreads" means the spreads between AWP and ASP as articulated in Direct Testimony of Raymond S. Hartman, Dkt. No. 3296, Attachment G.3.c, Ex. 14. The "spread" might, alternatively, be measured by the total dollars since providers were motivated by the dollars that he/she might receive by prescribing one drug rather than another. Plaintiffs do not concede the spreads used by Dr. Hartman at the Class 2/Class 3 trial are the spreads that should be applied to Class 1.

Statement 8. Plaintiffs concede, and the Court found, that published AWPs for Procrit and Remicade closely tracked the average selling prices.

Counter-Statement 8. Conceded to the extent "average selling prices" refers to those ASPs calculated during the Class 2/Class 3 trial. Plaintiffs encountered significant difficulties in the acquisition and interpretation of ASP data from Johnson & Johnson. Even Johnson &

Johnson's own expert, Mr. Dukes, testified that his many adjustments to ASP were simply based upon representations that were given to him by counsel for Johnson & Johnson or employees at Johnson & Johnson – representations that he, himself, did not test for accuracy. *See* Ex. 15 (Jayson S. Dukes Dep. (May 5, 2006) at 40:13-21; 41:22-42:16; 56:3-57:2; 71:7-13; 71:14-72:9; 80:22-81:14; 82:3-14; 85:4-7; 85:21-86:5; 87:21-88:4; 92:14-93:2; 98:19-99:3; 169:21-170:2).

Statement 9. Plaintiffs concede, and the Court found, that the spreads on Procrit and Remicade "never substantially exceeded the range of what was generally expected by the industry and government."

Counter-Statement 9. Plaintiffs concede that this was the Court's finding with regard to Class 2 and Class3, using the spreads calculated by Dr. Hartman during the Class 2/Class 3 trial. *In re AWP*, 491 F. Supp. 2d at 31. Plaintiffs do not concede that such a finding should be applied to Class 1.

Undisputed Facts Concerning Consumer Knowledge of Spreads

Statement 10. The consumers who testified at Track One trial had never heard of AWP.

Counter-Statement 10. Conceded.

Statement 11. Ms. Anna Choice testified at trial that she had no "knowledge regarding what AWP meant."

Counter-Statement 11. Conceded.

Statement 12. Ms. Rebecca Hopkins testified at trial that she did not "know anything about AWP at all."

Counter-Statement 12. Conceded.

Statement 13. Mr. Young, the class representative for Remicade, testified at his deposition that he had never heard of AWP, and that he did not know how or by whom AWP was calculated.

Counter-Statement 13. Conceded.

Statement 14. Mr. Shepley, the class representative for Procrit, testified at his deposition that he was not familiar with AWP.

Counter-Statement 14. Conceded.

Undisputed Facts Concerning the Absence of Damages

Statement 15. Plaintiffs concede that the application of Dr. Hartman's 30% yardstick to Procrit and Remicade yielded $0 in damages for Medi-Gap insurers in Class 2.

Counter-Statement 15. Conceded.

Statement 16. By definition, the same 30% yardstick would yield $0 in damages for Medicare beneficiaries in Class 1.

Counter-Statement 16. Plaintiffs concede that the same yardstick would yield $0 in damages for Class 1, but dispute that the 30% yardstick must or should be applied to Class 1.

Additional Statements of Disputed Material Fact Regarding J&J's Spread Marketing

A. J&J manipulated its pricing to create spreads

1. J&J manipulated its pricing to create spreads. When Procrit was launched, OBI considered Epogen a competitor. Ex. 33 (Pearson Dep. at 401:15-22, 402:1-5); Ex. 34 (Dempsey Dep. at 110:13-112:1). OBI kept Procrit's list price and AWP at parity with that of Epogen. Ex. 13 (PX 365). OBI attracted customers away from Epogen by offering customers greater rebates and discounts than Amgen. Ex. 35 (PX 270 at 544).

2. According to Cathleen Dooley, OBI's pricing strategy must enable physicians to receive an amount of reimbursement from Medicare that made them "whole" prior to collecting any co-payment revenue from the patient. *See* Ex. 9 (PX. 339 at 6807).

3. In order to offset Medicare's change in reimbursement on January 1, 1998 from AWP to AWP-5%, OBI twice raised Procrit's list price. During February 1997, OBI increased prices on its most popular 10,000 unit vial by 3.5%. Then, merely ten months later in January 1998, the same items were increased by an additional 1.8%. Ex. 36 (PX 237); Ex. 37 (PX 238).

This strategy ensured that the amount of reimbursement physicians received remained essentially unchanged after reimbursements were reduced in 1998.

4. Thomas Hiriak, OBI's Executive Director of Strategic Accounts and 30(b)(6) witness testified that the factors OBI considered in initiating Procrit price increases were "*[o]bviously margins and what could potentially happen to physicians' margins.*" Ex. 38 (Hiriak Dep. at 228:21-22, 229:1-13) (emphasis added). Other factors included "[t]iming since the last price increase, future marketplace changes, what potential reaction would be of our competitors. . . ." *Id.* at 229:6-9.

5. Cathleen Dooley referred to the spread between AWP reimbursement and acquisition cost as a "windfall" oncologists derived by administering Procrit through their practices. Ex. 8 (Trial Tr. Day 7 at 29-30 (Dooley)); Ex. 13 (PX 365); Ex. 39 (PX 979).

6. OBI viewed a decrease in the spread available to physicians as a threat to Procrit's sales. *See* Ex. 13 (PX 365); Ex. 39 (PX 979).

7. In 1997, OBI viewed Medicare's then proposed change in reimbursement from AWP to AWP – 5% as a threat to Procrit's sales. Ex. 8 (Trial Tr. Day 7 at 32-33 (Dooley)); Ex. 13 (PX 365).

8. OBI was aware that physicians had "significant economic incentives to prescribe supportive care drugs such as Procrit, due to revenue and profits from stocking and administering." Ex. 8 (Trial Tr. Day 7 at 44 (Dooley)); *see also* Ex. 40 (PX 334 at 6789).

9. OBI was also aware that oncologists administering Procrit could earn as much as $1,520.00 per patient per course of therapy. Ex. 8 (Trial Tr. Day 7 at 45-46 (Dooley)); *see also* Ex. 41 (PX 346).

B. J&J marketed the spread on Remicade

10. Centocor created the AWP spread and AWP and WAC prices with the intention of ensuring that doctors buying Remicade could make a profit. Centocor recognized that it was a "Key Strategic Imperative" to "set AWP at a level that preserves a modest margin for providers, ensures break-even potential for Medical providers, and is consistent with payer price elasticities." Ex. 7 (PX 249 at 97) (Centocor Initial Marketing Plan). Centocor knew doctors would not administer Remicade in their offices if there was no financial incentive to do so. Ex. 28 (Trial Tr. Day 5 at 92-93 (Hoffman)).

11. Centocor developed and implemented a multi-faceted Practice Management Program ("PMP") to show physicians how to make money by buying, infusing and billing for Remicade. The PMP began with the launch of Remicade in 1998 and continued for several years. Ex. 42 (Glassco Dep. at 20:14-21:22); Ex. 11 (McHugh Dep. at 252:15-253:14 and 355:10-356:13).

12. Among the PMP materials Centocor developed was a Financial Impact Worksheet, which a physician could use by filling in his acquisition cost for Remicade, the percent discount off AWP he would get in reimbursement (the AWP was pre-printed on the form) and his patient case load and the number of vials per patient. From this a physician could calculate his estimated "margin per vial" "revenue per patient" and "monthly revenue from Remicade." Ex. 43 (PX 252 at 8 and 4) (stating that one of the benefits of infusing Remicade is a "financial benefit to the physician's practice"). Centocor sales representatives would meet with physicians to discuss the worksheet and the "financial ramifications" of infusing Remicade. Ex. 28 (Trial Tr. Day 5 at 66-68 (Hoffman)). The Financial Impact Worksheet was also available on Centocor's website. *Id*. at 68:13-15.

13. Centocor also developed a more detailed and sophisticated software program that allowed physicians, with the assistance of a Centocor representative, to input detailed information about their various health plan payors and patient mix, to reach a more precise calculation about how much profit could be made from infusing Remicade. Ex. 44 (PX 289); Ex. 28 (Trial Tr. Day 5 at 69 (Hoffman)).

14. Keith Patterson, a former Centocor Marketing Director, admitted that Remicade was marketed on a physician's "Return To Practice" or profit, similar to AZ's Zolodex. Ex. 45 (Patterson Dep. at 311:21-313:17). Patterson also confirms the Centocor touted a physician's profit or "financial incentives" as a reason to conduct in-office infusions. *Id*. at 316:17-317:15.

15. Centocor executives held up as examples of good salesmanship reports of how sales representatives sold physicians on using Remicade based on the AWP spread. Ex. 46 (PX 272).

16. Centocor also brought scores of doctors to PMP seminars, where the economics and profit potential of the AWP spread on Remicade was explained directly. Ex. 42 (Glassco Dep. at 27:7-29:9). Centocor senior sales executive Laura Glassco provided the PowerPoint presentations she used for such seminars and walked through her presentation on how doctors can profit from both Medicare and private insurers by using the AWP spread on Remicade. *Id*. at 105:4-108:12, 109:15-19, 111:10-112:18; Ex. 47 (PX 254). Glassco expressly used the term "profit" to highlight the AWP spread on Remicade. Ex. 47 (PX 254 at 300); Ex. 42 (Glassco Dep. at 14:9-17:8).

17. At the same time Centocor was operating its wide-scale PMP campaign, its sister J&J Company, OBI, was telling its employees that it "is absolutely inappropriate to sell product based upon the difference between AWP and acquisition price." Ex. 48 (DX 2767).

18. Over a year after this case was filed, in June 2002, Centocor reversed its prior position and told its employees not to answer physician questions about Return To Practice or revenues from Remicade, saying that such answers would violate Centocor's policies. Ex. 49 (DX 2835 (questions 3, 4, 12, 14c and 15)); Ex. 42 (Glassco Dep. at 113:17-114:5).

19. After trial, Plaintiffs introduced a Complaint brought by a former Centocor employee where she alleged that she was involved in the marketing of Remicade by reference to the money that could be made by describing the drug, and, specifically, used a PowerPoint presentation that contained an audible "Ka-Ching!" sound while a slide detailed the profit potential of Remicade. *See* Notice of Supplemental Evidence Regarding the Marketing of Remicade or for Leave to Take Discovery of the "Ka-Ching" Marketing Tool, Dkt. No. 3867 and Attachment A thereto.

C. J&J marketed the spread on Procrit

20. Prior to bringing Procrit to market, OBI was aware that the amount of reimbursement that physicians, hospitals and retail pharmacists received was a primary driver in those markets. Ex. 38 (Hiriak Dep. at 92:1-93:16, 94:1-95:12). By 1993, OBI knew that oncologists made a "significant" portion of their revenue from the drugs they prescribed. *Id*. at 96:13-15, 96:18-97:14, 156:21-157:10, 157:12-15, 159:18-19, 160:3-18.

21. Prior to at least November 2001, there was no writing or written policy at J&J or OBI that advised any segment of OBI's sales force against marketing Procrit's spread to customers. Ex. 50 (PX 330).

22. Sales materials used by OBI field sales managers and representatives highlighted the financial benefit of Procrit's spread to customers. Sales training materials presented at a three-day 1992 Regional Training Workshop held in Houston, Texas were distributed to OBI's sales representatives from the Houston, Dallas, Atlanta, Florida, Carolina and Philadelphia

Divisions. Ex. 35 (PX 270 at 62508). Among these materials were included: (i) A document reflecting the amount of profit a physician will "clear" under Medicare based on the difference between acquisition cost (including rebates) and Medicare reimbursement for the various Procrit dosages (*id*. at 62543); (ii) a document showing that the overall cost of Procrit, after 11% rebates, is far below that of its competitor Epogen (and therefore has a greater spread since it is reimbursed at the identical amount) (*id*. at 62544); (iii) a document advising the sales force to highlight the "profitability of 8% retail rebate" (*id.* at 62533) and to "[k]now how to explain Procrit Profit to the Pharmacist" (*id*. at 62599). This document was intended to be a standardized training program for all newly hired field sales representatives.

23. OBI's marketing efforts for Procrit included providing value-added services to physicians in obtaining reimbursement for Procrit. OBI created the PROCRITline, a reimbursement hotline to assist physician offices, and a reimbursement assurance program that guaranteed reimbursement for physicians. *Id*. at 62532-42.

24. OBI's "1998 Reimbursement Update and Challenges" admits that from at least the early 1990s through late 1997, the Procrit "[m]arket [was] driven by MD profit incentives." Ex. 51 (PX 242 at 58922).

25. In 1999, a McKinsey and Company report for OBI concluded that as of that date, Procrit had primarily been "[u]sed by physicians because it is economically attractive." Ex. 40 (PX 334 at 6807). This report also found that "physicians have significant economic incentives to prescribe supportive care drugs such as Procrit, due to revenue and profits from stocking and administering." Ex. 40 (PX 334 at 6789).

26. McKinsey & Company notes that "[f]or private physicians, stocking and administering Procrit yield significant profit opportunities." The report also highlighted

physician statements that "[m]y practice makes $6-8,000 per month on Procrit." The report also provides a graph of "physician economics" demonstrating the amount of profit physicians receive from prescribing Procrit. *Id*. at 6792. Further emphasizing the need for providing economic incentives to physicians, under the heading "Influencing Physician Usage" McKinsey notes that the "Implied Strategy" is that "OBI must preserve positive economics for physicians" and "if economics deteriorate" then "[s]tandard of care and 'habitual' prescribing increases in importance." *Id*. at 6810.

27. A former OBI Divisional Sales Manager, John Hess, sent a memorandum to his sales team (responsible for Minnesota, Wisconsin, Iowa, Nebraska, the Dakotas, Missouri and Kansas) summarizing an OBI Western Region Marketing Strategy meeting. This memo details the main strategies that an OBI sales and marketing manager recommended to increase sales to high-user oncology clinics, including "the ability to tactfully discuss how an office can profit from providing Procrit in the office." Ex. 52 (PX 268 at 63656). The memo notes that "[t]his discussion can be brought up whenever an office raises the objection about the expense of Procrit therapy and how they are at risk of losing money when they purchase expensive medications such as Procrit. The office needs to understand that there is profit associated with Procrit and that they are also protected from loss under our reimbursement Assurance Program." *Id*. The memo also describes a "return on equity for Procrit" explanation that sales representatives were to use on visits to oncology practices and advised that "[w]hen reviewing with a physician or office manager you should ask for their real numbers." *Id*. at 63656.

28. The document also specifically quantifies for sales representatives the: (i) Non-Medicare per patient profit, and (ii) Medicare per patient profit, for physicians prescribing Procrit over a week, month, six months and year. *Id*. In connection with these examples,

Mr. Hess instructs: "When reviewing this information simply draw out the scenario on a piece of scratch paper asking for the office billing fee, injection fee, and acquisition fee based on Medicare or non-Medicare. Give this a try in those offices raising the objection of cost and risk to the office." *Id*. at 63657. Mr. Hess stated that he did not believe that the content of his memorandum violated any written or unwritten policy at OBI at that time. Ex. 53 (Hess Dep. at 96:18-97:1).

29. When confronted with the Hess Memorandum, James Robbins, OBI National Field Sales Director, conceded that it encouraged spread marketing.

> Q: And isn't that an incentive –we're referring again to the Exhibit Robbins 021. Isn't that an incentive for the doctor to put as many patients as he can on Procrit and to keep them on it for as long as possible?
>
> Mr. Schau: Object to form.
>
> Mr. Robbins: There's two parts to your question, and the answer's not the same for both. On the first part, assuming that John's [Hess] numbers are correct there, the first part would be yes."

Ex. 54 (Robbins Dep. at 466:5-15).

30. An OBI memorandum dated March 22, 1995, shows that sales representatives successfully promoted margin to convert physician practices to purchase Procrit 20,000 unit put-ups instead of Procrit 10,000 put-up. Patricia Hawley, an OBI sales representative in its Orlando District, noted that among the key factors that were successful in persuading physician practices to convert to the higher dosages were the "[g]ood profit margin between the $96.00 Medicare payment and the $80.75 promotion price for administering 10,000 units of the multidose vial." Ex. 55 (PX 269 at 63648).

31. A letter dated September 28, 1998, from Brock Weathers to Michael Kalson, M.D. at Academy Orthopaedics [sic], follows up a visit by explicitly laying out the costs and reimbursement of Procrit. Ex. 56 (PX 364).

32. A presentation titled "Procrit Reimbursement Alternatives," was developed and presented by Documedics, with the input and approval of OBI's Cathleen Dooley. Ex. 57 (PX 331). Bobbi Buell, the presenter, on behalf of OBI, asks, "Can you make money????", *id*. at 61833, and states "[d]rugs have paid well under part B." *Id*. at 61838. Ms. Buell concludes her presentation with the question "Should you give Procrit?" and her first reason in support thereof is that it provides "Additional revenue." *Id*. at 61841.

33. In response to Amgen's Aranesp introduction in 2001, OBI sought to increase the level of rebates and discounts that it offered to its customers. Ex. 54 (Robbins Dep. at 138-39).

34. Based upon the recommendation of Dr. Bell, Defendants' expert, OBI delivered an economic message that a physician would be better off economically by staying with Procrit due to the comparatively higher cost of Aranesp to physicians and patients at higher doses, and the costs of switching from Procrit to Aranesp in terms of a loss of rebates, discounts and other administrative costs. *See* Ex. 59 (PX 343), Ex. 60 (PX 344). Dr. Bell also advised OBI to develop a spreadsheet that doctors could use to calculate their profits. Ex. 60 (PX 344).

35. OBI developed computer CD-Rom materials that were designed to show a physician the economic advantage gained by continuing to dispense Procrit, rather than switch to Aranesp, due to the comparative value of the discounts and rebates OBI offered. Ex. 61 (PX 248). Testimony indicates that some of the CDs shown to physicians contained references to AWP. Ex. 54 (Robbins Dep. at 295:4-19).

D. J&J hid the true price of its products

36. When discussing Remicade costs with health plans, Centocor was careful not to reveal the physicians' acquisition cost, but only to reference the AWP price. Centocor's Cost Minimization Model or Cost Comparison Model software was used with health plans to encourage them to provide reimbursement for Remicade. Ex. 27 (PX 285). That software only references AWP, not WAC or acquisition cost. Centocor did not show health plans their various marketing tools that revealed physician acquisition prices or profit. Ex. 28 (Trial Tr. Day 5 at 83-84 (Hoffman)).

37. Centocor's Senior Director for Reimbursement Services, Michael Ziskind, articulated Centocor's policy of hiding acquisition prices from Third-Party Payors and Class members in a July 6, 1999 memo on the background of AWP and spread. Ziskind explained that the "'cost of therapy' varies widely based on the audience." Ziskind then explained Centocor's strategy was to not mention both wholesaler cost and AWP in the same conversation, because to do so would "set payers' expectations too low" and would "highlight spread more than we would like." Ex. 29 (PX 260).

38. On the one occasion where Centocor did report the price of Remicade to the Federal government, it hid the truth. When Centocor applied for a specific J-Code for Remicade, the application asked for Remicade's wholesale price. Centocor responded by saying that the wholesale price was AWP and that the retail price was equivalent to WAC. Ex. 30 (PX 261). Those statements were directly contrary to the fact that Remicade's WAC, not AWP, was effectively the wholesale price. Ex. 28 (Trial Tr. Day 5 at 59:14-17 (Hoffman) (wholesale price close to WAC) and 59:21-25 (Remicade had no retail price)).

39. At trial, Centocor highlighted the fact that it worked with insurers to help them lower their cost of infusing Remicade, specifically citing to work done with Aetna. *Id.* at 103-

07. However, at the same time, Centocor was also telling its physician customers to threaten Aetna by saying the doctors would send Remicade treatments back to the hospital unless Aetna raised reimbursement rates. Ex. 31 (PX 302 at 32731).

40. Both Centocor and OBI's rebate contracts contained confidentiality clauses, which prevented the parties receiving rebates from revealing the amount, or even the existence of rebates on Remicade or Procrit. Ex. 32 (DX 2804 (sec. 1.5 and 3.1)).

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

In re Pharmaceutical Industry Average Wholesale Price Litigation
Master Case No. 01-cv-12257, MDL 1456

I, Steve W. Berman hereby certify that I am one of Plaintiffs' attorneys and that, on January 15, 2010, I caused a copy of ***Plaintiffs' Local Rule 56.1 Counter-Statement of Disputed Material Facts in Opposition to the J&J Defendants' Post-Remand Motions for Summary Judgment*** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

s/ Steve W. Berman
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